EXHIBIT B

IN THE COMMON PLEAS COURT OF ROSS COUNTY, OHIO CIVIL DIVISION

STATE OF OHIO *ex rel.* MIKE DeWINE, Ohio Attorney General,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; AND DOES 1 THROUGH 100, INCLUSIVE,

Defendants.

Case No. 2017 CI 216

COMPLAINT NUSBAUM

JURY TRIAL DEMANDED AND ENDORSED HEREON

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COMPLAINT

JURY TRIAL DEMANDED AND ENDORSED HEREON

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Plaintiff, the State of Ohio, by and through its Attorney General, Mike DeWine, (hereinafter "Ohio" or "the State"), upon personal knowledge as to its own acts and beliefs, and upon information and belief as to all matters based upon the investigation of counsel, alleges as follows:

I. INTRODUCTION

1. Drug companies should never place their desire for profits above the health and well-being of their customers or the communities where those customers live. Because they know prescribing doctors and other health-care providers rely on drug companies' statements in making treatment decisions, drug companies must tell the truth when marketing their drugs and ensure that their marketing claims are supported by science and medical evidence.

2. Defendants broke these simple rules and helped unleash a healthcare crisis that has had far-reaching financial, social, and deadly consequences in the State of Ohio.

3. Defendants manufacture, market, and sell prescription opioids (hereinafter "opioids"), including brand-name drugs like Oxycontin and Percocet, and generics like oxycodone and hydrodone, which are powerful narcotic painkillers. Historically, because they were considered too addictive and debilitating for the treatment of chronic pain (like back pain, migraines and arthritis),[1] opioids were used only to treat short-term acute pain or for palliative (end-of-life) care.

4. However, by the late 1990s, and continuing today, each Defendant began a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, a far broader group of patients much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each

[1] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain. As to the risks, Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Conversely, Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no "good evidence" to support Defendants' claims.

5. Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians Defendants recruited for their support of Defendants' marketing messages. Borrowing a page from Big Tobacco's playbook, Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Defendants

persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

6. Each Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA ("2016 CDC Guideline"). Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into settlements agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint in other jurisdictions. Yet even now, each Defendant continues to misrepresent the risks and benefits of long-term opioid use in Ohio and continues to fail to correct its past misrepresentations.

7. Defendants also formed an opioid marketing enterprise in violation of the Ohio Corrupt Practices Act for the purpose of illegally promoting the widespread use of opioids for chronic pain.

8. Defendants' efforts were wildly successful. Opioids are now the most prescribed class of drugs; they generated $11 billion in revenue for drug companies in 2014 alone. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for

legitimate pain."[2] This epidemic, fueled by opioids lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

9. It is hardly necessary to say – in this County or this State – that Ohio is now awash in opioids and engulfed in a public health crisis the likes of which have been seen before. In 2012, the total number of opioid doses prescribed to Ohio patients soared to 793 million – enough to supply every man, woman and child in the state with ***68 pills each***.[3] In 2016 alone, 2.3 million Ohio patients – roughly 20% of the state's population – were prescribed an opioid drug.[4] The Ohio Automated RxReporting System ("OARRS"), the computer system that tracks how drugs are prescribed and dispensed, shows that in 2015, 1,663,614 opioid pills, or 182.2 per patient or 21.3 per capita, were dispensed in Ross County alone.[5]

10. The result of Ohio's opioid crisis has been catastrophic. Opioids have become the main source of unintentional drug overdose in the state and, due to the vast supply of opioids, the number of annual deaths attributable to unintentional drug overdoses has rapidly increased in

[2] Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org/.

[3] Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010; Ohio Opiate Action Team, Fighting Prescription Drug Abuse, Rx Prescribing Guidelines; Ohio Automated RX Reporting System, 2016 Annual Report. OARRS tracks only legitimately-prescribed drugs and does not track illegal use.

[4] Ohio Automated RX Reporting System, 2016 Annual Report.

[5] *See* Alan Johnson, *Oxycontin, other narcotic pills still plentiful in Ohio* (Jan. 15, 2017), available at: http://www.cantonrep.com/news/20170115/oxycontin-other-narcotic-pain-pills-still-plentiful-in-ohio.

recent years.[6] 2016 saw a thirty-six (36%) increase in unintentional fatal overdoses in the State of Ohio from the previous year, when Ohio led the nation in the total number of fatal overdoses.[7] This total is expected to go higher as coroners in six smaller counties update their numbers.[8]

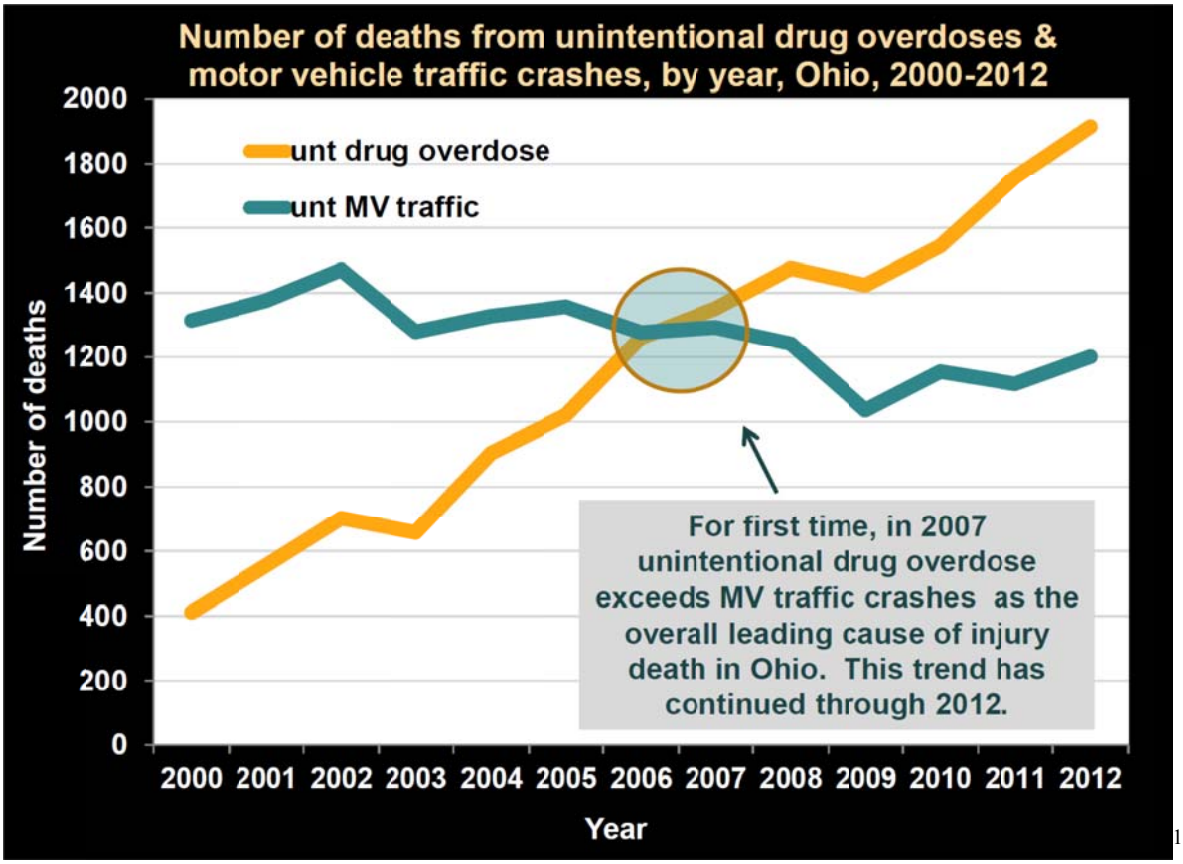
11. Unintentional drug-related overdoses surpassed car accidents as the leading cause of accidental death in Ohio in 2007 and, in response to the increasing number of fatalities, city and county health commissioners in Ohio declared a public health emergency in January 2010.[9] Since that time, numerous Ohio counties have followed suit. Nevertheless, overdose rates have continued to grow.

[6] Ohio Department of Health, 2015 Ohio Drug Overdose Data General Findings.

[7] *Newspaper: Ohio had more than 4,000 overdose deaths in 2016* (May 28, 2017), available at: http://www.dispatch.com/news/20170528/newspaper-ohio-had-more-than-4000-overdose-deaths-in-2016.

[8] *Id.*

[9] Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010.



[10]

12. But even these alarming statistics do not fully illustrate the toll of prescription opioid abuse on patients and their families, as the dramatic increase in opioid prescriptions to treat chronic pain has resulted in a population of addicts who seek drugs from doctors. Efforts by physicians to reverse course for a chronic pain patient with long term dependence on opioids are often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that are diverted to supply these patients.

13. Prescription opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on State agencies that address heroin use and

[10] Ohio Department of Health, Ohio's Opioid Epidemic: An Overview of the Problem; *see also* ODH Office of Vital Statistics.

addiction. Individuals who are addicted to prescription opioids often transition to heroin because it is a less expensive, readily available alternative that provides a similar high.[11]

14. An estimated 1,162,000 Ohio citizens suffer from chronic pain,[12] which takes an enormous toll on their health, lives and families. These patients deserve both appropriate care and the ability to make decisions based on accurate, complete information about treatment risks and benefits. But Defendants' deceptive marketing campaign deprived Ohio patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

15. Defendants' conduct has also exacted, and foreseeably so, a financial burden on the State of Ohio. The Ohio Department of Medicaid and Bureau of Workers' Compensation have spent hundreds of millions of dollars on opioid prescriptions for chronic pain. In addition, both the Department of Medicaid and Bureau of Workers' Compensation have spent tens of millions more on costs directly attributable to the flood of opioids Defendants unleashed on the State, including costs for addiction treatment and the treatment of babies born addicted to opioids.

16. To redress and punish these violations of law, the State of Ohio, by and through Attorney General Mike DeWine, seeks damages for the amounts the Department of Medicaid and the Bureau of Workers' Compensation have paid for excessive opioid prescriptions and in connection with the results of those prescriptions (*e.g.,* addiction treatment costs). The State also

[11] Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010.

[12] Report of the Ohio Compassionate Care Task Force (Mar. 2004).

seeks a declaration that Defendants' conduct has violated Ohio law, an order requiring Defendants to cease their unlawful promotion of opioids and correct their misrepresentations and an order requiring Defendants to abate the public nuisance they have created and knew their actions would create. The State seeks restitution for Ohio consumers who, like the State, paid for excessive prescriptions of opioids for chronic pain. The State also seeks punitive damages, treble damages, and attorneys' fees and costs, in addition to granting any other equitable relief authorized by law.

II. JURISDICTION AND VENUE

17. This Court has jurisdiction over this matter pursuant to R.C. 2307.382 (as to the Ohio Products Liability Act claim); 2305.01 (as to the common law public nuisance claim, common law fraud and Medicaid Fraud claim); 1345.04 (as to the Ohio Consumer Sales Practices Act claim) and 2923.34 (as to the Ohio Corrupt Practices Act claim).

18. This Court has personal jurisdiction over Defendants as they conduct business in Ohio, purposefully direct or directed their actions toward Ohio, and/or have the requisite minimum contacts with Ohio necessary to constitutionally permit the Court to exercise jurisdiction.

19. Venue is proper in Ross County pursuant to Civ. R. 3(B)(2) and Civ. R. 3(B)(3). Each Defendant (1) conducted activity that gave rise to the State's claims for relief; and (2) part of the claims for relief arose in Ross County.

III. PARTIES

A. Plaintiff

20. This action is brought for and on behalf of the sovereign State, by and through Mike DeWine, the duly-elected and current Attorney General and chief law officer for the State and all of its departments.

B. Defendants

21. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

22. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S. and Ohio. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

23. In May 2007, Purdue entered into an agreed final judgment with the State of Ohio, based principally on Purdue's direct promotion of OxyContin up to May 8, 2007, the effective date of the Final Judgment. In this Complaint, the State does not seek to enforce any provision of that final judgment, and is not seeking any relief against Purdue under any state consumer protection law as defined by section (I)(1)(M) and footnote 2 of the final judgment based on any conduct by Purdue that occurred at any time up to and including May 8, 2007, relating to Purdue's promotional and marketing practices regarding OxyContin. The State does, however, assert claims arising under Ohio law independent of the final judgment, and seeks restitution, in addition to declaratory and injunctive relief, as afforded by law.

24. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd.

acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

25. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and Ohio. Actiq and Fentora have been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[13] In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

26. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Ohio, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in Ohio, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for

[13] Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain.

Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales." Through interrelated operations like these, Teva Ltd. operates in Ohio and the rest of the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon.")

27. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals,

Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen.")

28. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Ohio, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

29. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo.")

30. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Ohio. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Ohio, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

31. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and

the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis.")

32. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. and Ohio. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

33. The State lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive, and they are therefore sued herein pursuant to Civil R. Rule 15(D). The State will amend this Complaint to show their true names and capacities if and when they are ascertained. The State is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in

some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

IV. FACTUAL ALLEGATIONS

34. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

35. To take advantage of the lucrative market for chronic pain patients, each Defendant developed a well-funded marketing scheme based on deception. Each Defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use – statements that benefited not only themselves and the third-parties who gained legitimacy when Defendants repeated those statements, but also other Defendants and opioid manufacturers. Yet these statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations.

A. Defendants Used Multiple Avenues To Disseminate Their False And Deceptive Statements About Opioids.

36. Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Ohio. Defendants also deployed seemingly unbiased

and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State.

1. Defendants spread and continue to spread their false and deceptive statements through direct marketing of their branded opioids.

37. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

38. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Ohio.

39. Second, each Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. Defendants have not corrected this misinformation. Instead, each Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent $168 million on detailing branded

opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis.

40. Defendants' detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

41. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

42. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, Defendants purchase, manipulate and analyze some of the most

sophisticated data available in *any* industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, Defendants *know* their detailing to doctors is effective.

43. Defendants employed the same marketing plans and strategies and deployed the same messages in Ohio as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

44. Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

2. Defendants used a diverse group of seemingly independent third parties to spread false and deceptive statements about the risks and benefits of opioids.

45. Defendants also deceptively marketed opioids in Ohio through unbranded advertising – *i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising,

Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

46. Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

47. Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	**Opana ER Advertisement (Branded)**
"People who take opioids **as prescribed usually do not become addicted**."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

a. Key Opinion Leaders ("KOLs")

48. Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

49. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Defendants.

50. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

51. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to direct and exert control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

52. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use.

Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

53. Thus, even though some of Defendants' KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, those admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide and throughout the State of Ohio in Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

54. Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

(1) Russell Portenoy

55. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

56. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the

American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Defendants.

57. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast in Ohio and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[14]

58. To his credit, Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[15] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[16]

(2) Lynn Webster

59. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr.

[14] Good Morning America television broadcast, ABC News (Aug. 30, 2010).

[15] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec. 17, 2012.

[16] *Id.*

Webster was President in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

60. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

61. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

62. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach Ohio doctors.

63. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[17]

b. Front Groups

64. Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

65. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure that the Groups would generate only the messages Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and

[17] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, MILWAUKEE WISC. J. SENTINEL (Feb. 19, 2012).

serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

66. Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

(1) American Pain Foundation ("APF")

67. The most prominent of Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at $1.7 million.

68. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Ohioans.

69. In addition to Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue) Russell Portenoy, and Scott Fishman (a KOL from the University of California, Davis who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue), all of whom served on APF's Board and

reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

70. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

71. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

72. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

73. APF assisted in other marketing projects for drug companies. One project funded by another drug company – *APF Reporter's Guide: Covering Pain and Its Management* (2009) – recycled text that was originally created as part of the company's training document.

74. The same drug company made general grants, but even then it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year – this would be a very good issue on which to use some of that. How does that work?"

75. The close relationship between APF and the drug company was not unique, but mirrors relationships between APF and Defendants. APF's clear lack of independence – in its finances, management, and mission – and its willingness to allow Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

76. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

(2) American Academy of Pain Medicine ("AAPM")

77. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

78. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

79. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[18]

80. AAPM's staff understood they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

[18] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829.

81. In addition, treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

82. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.

83. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

84. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan

Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Ohio during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

85. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

86. Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum (PCF), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which Defendants determined would reduce prescribing.

B. Defendants' Marketing Scheme Misrepresented The Risks And Benefits Of Opioids.

87. To convince doctors and patients in Ohio that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive,

Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them, and continue to spread them today.

1. Defendants falsely trivialized or failed to disclose the known risks of long-term opioid use.

88. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

89. ***First***, Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and deceptive claims are described below:

a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.

h. Detailers for Purdue, Endo, Janssen, and Cephalon in Ohio minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

90. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an

alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including . . . opioid use disorder” and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”

91. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

92. The warnings on Defendants’ own FDA-approved drug labels caution that opioids “expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death,” that the drugs contain “a substance with a high potential for abuse,” and that addiction “can occur in patients appropriately prescribed” opioids.

93. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.” Endo had claimed on its www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree

that patients treated with prolonged opioid medicines usually do not become addicted," but the State found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in Ohio.

94. ***Second***, Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudoaddiction" – a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue – and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. Responsible Opioid Prescribing remains for sale online. The 2012 edition, which also remains available online, continues to teach that pseudoaddiction is real.

b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

95. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

96. Even one of the Defendants has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the State of New York, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'" Consistent with this, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York. Endo, however, remains free to do so in Ohio.

97. ***Third,*** Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

98. Once again, the 2016 CDC Guideline confirms the falsity of these misrepresentations. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for

[opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

99. ***Fourth***, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

100. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.

101. Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties,

including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

102. ***Fifth***, Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during the time period of this Complaint on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

f. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.

h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,"[19] challenging the correlation between opioid dosage and overdose.

103. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

[19] www.cpdd.org.

104. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

105. ***Finally***, Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.[20]

106. More specifically, Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse." Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

107. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for

[20] Catherine S. Hwang, *et al.*, *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175(2) JAMA INTERN. MED. 302-4 (Dec. 8, 2014).

deterring or preventing abuse," noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."

108. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

2. Defendants grossly overstated the benefits of chronic opioid therapy.

109. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today.

110. For example, Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples are described below:

a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

f. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in 2012.

g. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

h. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

i. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids

allowed a patient to "continue to function." This video is still available today on YouTube.

j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today.

k. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

111. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

- "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."
- "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
- "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

112. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

113. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned

Actavis, in response to its advertising described in paragraph 40, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[21] And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

114. Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

115. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does

[21] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm259240.htm.

not last for 12 hours – a fact that Purdue has known at all times relevant to this action. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

116. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continue to tell Ohio doctors that OxyContin lasts a full 12 hours.

117. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

> Oxycontin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleeps though the night, which is often impossible with short-acting medications.

> For many of those serviced by Pain Care Amici, Oxycontin has been a miracle medication.[22]

3. Defendants also engaged in other unlawful, unfair, and fraudulent misconduct.

118. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

119. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The

[22] *See* Reply Br. of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, 2004 WL 1637768, at *4.

CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

- Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

- In December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

120. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

121. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles

clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

122. The State of New York's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

123. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

C. Defendants Targeted Susceptible Prescribers And Vulnerable Patient Populations.

124. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including Ohio. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations.

125. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking

opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

D. Although Defendants Knew That Their Marketing Of Opioids Was False And Deceptive, They Fraudulently Concealed Their Misconduct.

126. Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

127. Moreover, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Defendants disguised their own role in the deceptive

marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

128. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the State.

129. Thus, Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that the State now asserts. The State did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

E. By Increasing Opioid Prescriptions And Use, Defendants' Deceptive Marketing Scheme Has Fueled The Opioid Epidemic And Devastated Ohio Communities.

130. Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.[23]

131. Defendants' deceptive marketing scheme caused and continues to cause doctors in Ohio to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

132. Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

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[23] Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), *available at* http://www.hazeldenbettyford.org/about-us/news-and-media/pressrelease/doctors-missing-questions-that-could-prevent-opioid-addiction.

133. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Ohio. In August 2016, then-U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

134. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

135. Contrary to Defendants' misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet.[24] Numerous doctors and substance abuse counselors note that many of their patients who misuse

[24] *See* U.S. Dep't of Health & Human Servs., *2011 National Survey on Drug Use and Health* (Sept. 2012).

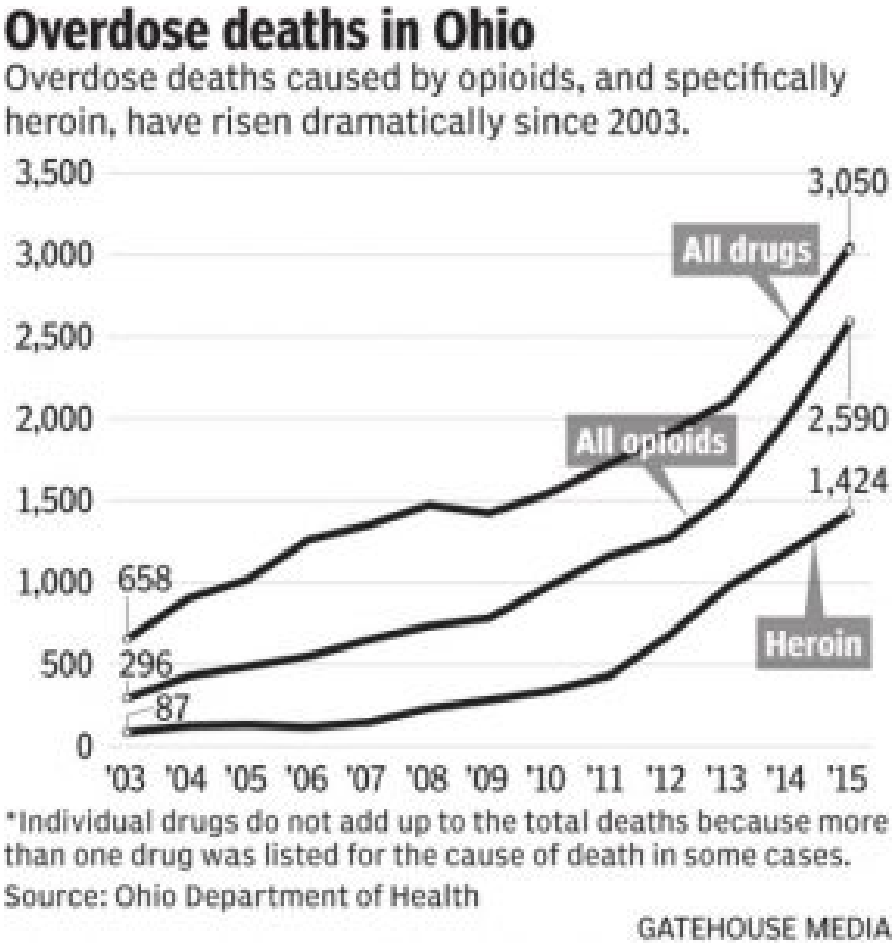
or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

136. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. Opioids are by far the most commonly prescribed class of substances in Ohio. Between 2011 and 2015, over ***3.8 billion doses*** of opioid medication were prescribed in Ohio alone.[25] In 2015, 85 percent of all accidental drug overdose deaths in the state were caused by an opioid.[26] It is unsurprising, given the widespread epidemic, that a recent poll found that 40% of adults in Ohio knew someone who had overdosed due to a prescription painkiller and 56% knew someone who had overdosed from heroin.[27]

[25] 2015 Ohio Drug Overdose Data: General Findings; State of Ohio Board of Pharmacy, Ohio Automated Rx Reporting System.

[26] Ohio Department of Health, 2015 Ohio Drug Overdose Data General Findings; *see also* Governor's Cabinet Opiate Action Team, http://fightingopiateabuse.ohio.gov/.

[27] Ohio Health Issues Poll (April 2016). https://www.interactforhealth.org/upl/Heroin_use_prescription_drug_misuse_still_climbing_in_Ohio.pdf; Ohio Department of Health. (September 2015). 2014 Ohio Drug Overdose Preliminary Data: General Findings. Retrieved Oct. 22, 2015, from www.healthy.ohio.gov/vipp/data/rxdata.aspx.



137. When compared to previous drug overdose epidemics in Ohio, the current prescription drug epidemic is responsible for considerably more deaths. In 2010, mortality rates were 4 to 5 times higher than the rates during the "black tar" heroin epidemic in the mid-1970s and more than 3 times what they were during the peak years of the crack cocaine epidemic in the early 1990s.[28] From 2000 to 2015, drug overdose fatalities in Ohio increased by 642% – equating to 8 deaths per day or 1 death every 3 hours in 2015.[29] In 2014 and 2015, Ohio had the greatest number of deaths in the nation from synthetic opioids – with 1 in every 14 deaths from

[28] Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010.

[29] Ohio Department of Health, https://www.odh.ohio.gov/health/vipp/drug/dpoison.aspx (last visited May 12, 2017).

synthetic opioids in the United States occurring in the state.[30] In 2015, the number of opioid-related overdose deaths in Ohio reached a staggering 2,590.[31]

Table 1. Unintentional Drug Overdose Deaths of Ohio Residents Involving Specific Drug(s), as Mentioned on Death Certificate, by Year, 2003-2015[1-3]

Drug Category	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	% of 2015 deaths
All opioids*	296	429	489	551	631	733	783	980	1,163	1,272	1,539	2,020	2,590	84.9%
Heroin	87	124	131	117	146	233	283	338	431	680	983	1,196	1,424	46.7%
Fentanyl					4	6	7	5	0	75	84	503	1,155	37.9%
Prescription opioids**	221	319	388	462	504	538	543	692	795	628	644	672	667	21.9 %
Benzodiazepines	38	69	90	121	133	154	211	300	376	311	328	420	504	16.5%
Cocaine	140	221	223	317	287	252	220	213	309	326	405	517	685	22.5%
Alcohol	40	38	58	89	135	181	173	195	226	282	304	383	380	12.5%
Methadone	55	116	144	161	176	168	169	155	156	123	112	103	108	3.5%
Hallucinogens	7	8	8	10	13	14	9	26	31	31	43	49	61	2.0%
Barbiturates	5	3	5	3	7	3	5	13	11	6	10	6	19	0.6%
Other/unspecified drugs only***	154	256	289	378	453	475	396	343	376	389	319	274	194	6%
Multiple Drug Involvement								888[4]	980[5]	1,016[6]	1,014[7]	1,321[8]	1,747[9]	
Total unintentional poisoning deaths	658	904	1,020	1,261	1,351	1,473	1,423	1,544	1,772	1,914	2,110	2,531	3,050	
Age-adjusted annual death rate per 100,000	5.8	7.9	8.9	11.0	11.7	12.8	12.5	13.7	15.6	17.1	18.8	22.8	27.7	

Source: Ohio Department of Health, Bureau of Vital Statistics; Analysis by ODH Injury Prevention Program.

138. Opioid-related death tolls are rising at such a rapid pace that cities and counties are unable to keep up logistically. As an example, in 2016, one coroner's office had to use refrigerated trucks to store bodies for an entire week because the city was unable to process cases as fast as individuals were fatally overdosing. In 2017, the same coroner's office was forced to

[30] The Henry J. Kaiser Family Foundation Overdose Deaths, 2014 and 2015.

[31] Courtney Astolfi, *Report: Ohio ground-zero for opioid overdose deaths*, Cleveland.com (Nov. 30, 2016), *available at*: http://www.cleveland.com/metro/index.ssf/2016/11/report_ohio_ground-zero_for_op.html.

request, for the first time ever, that a local funeral parlor provide temporary storage for bodies that it simply lacked the capacity to hold.[32]

139. Defendants' deceptive marketing scheme has also had a significant detrimental impact on children in Ohio in a number of ways. First, the overprescribing of opioids for chronic pain has made the drugs more accessible to school-aged children, who come into contact with opioids after they have been prescribed to friends or relatives in the same household. An Ohio Department of Health survey of high school students revealed that, from 2011 to 2013, 12.8 percent of students illegally used prescription painkillers like OxyContin.[33]

140. Additionally, Ohio's child protection agencies experienced a 9 percent increase in the number of children – nearly 1,100 – in foster care between December 2011 and December 2015, driven by parental drug addiction.[34] Seventy percent of infants placed in Ohio's foster care system are children of parents with opiate addictions.[35] Children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma, which makes these cases more expensive to deal with.[36] Consequently, the State of Ohio spends an estimated $45 million per year for placement costs of children in custody due to parental use of heroin or other opiates.[37]

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[32] Kimiko de Freytas-Tamura, *Amid Opioid Overdoses, Ohio Coroner's Office Runs Out of Room for Bodies*, N.Y. Times (Feb. 2, 2017).

[33] Ohio Department of Health, 2013 Ohio Youth Risk Behavior Survey: Illegal Drug Use and Prescription Drug Abuse.

[34] Public Children Services Association of Ohio, Ohio's Opiate Epidemic and Child Protection (2016).

[35] Ohio Child Welfare Opiate Engagement Project (Sept. 2014).

[36] Trista Thurston, *Drug addiction drives spike in Ohio foster care*, Newark Advocate (Mar. 23, 2017).

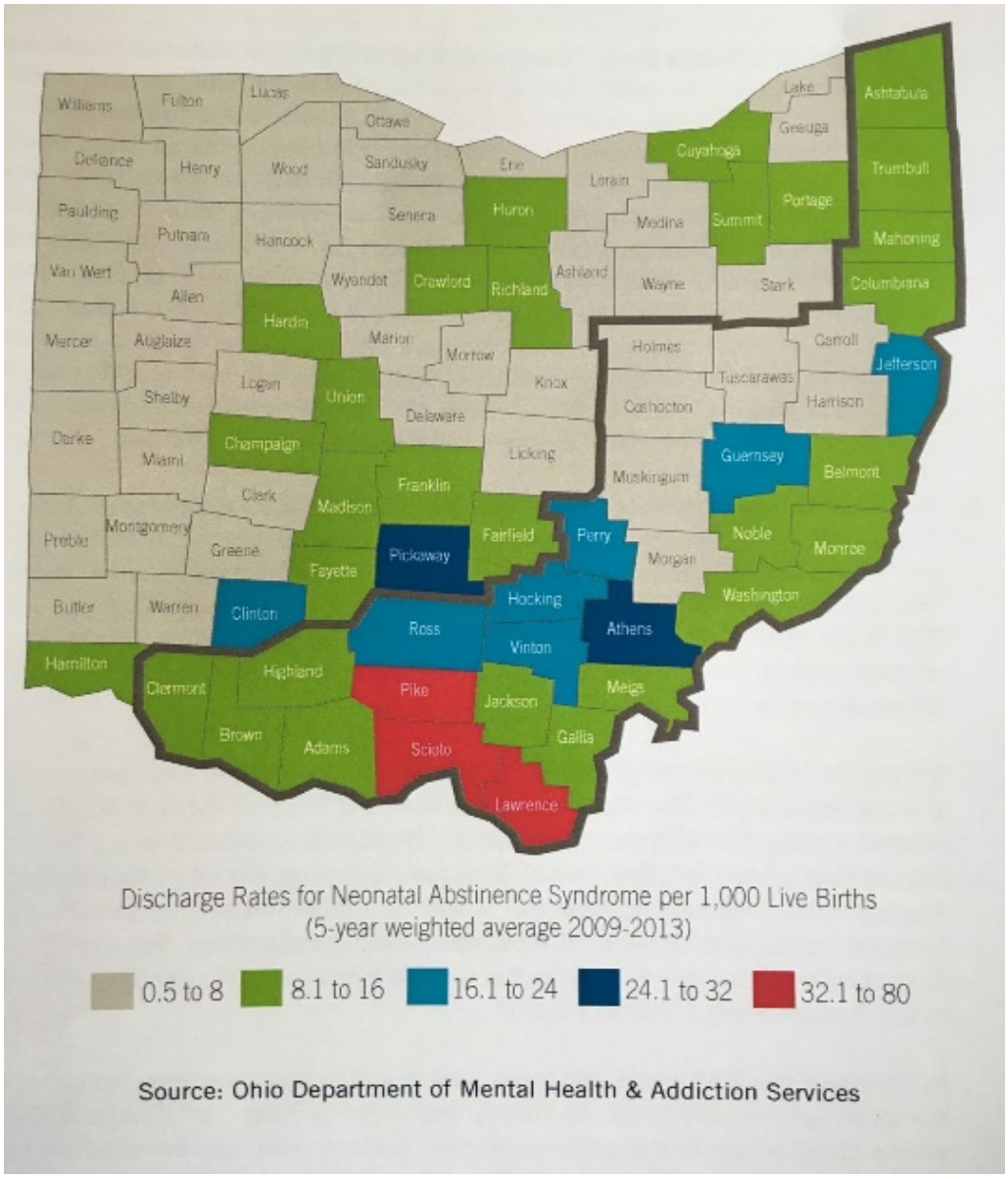
[37] Public Children Services Association of Ohio, Ohio's Opiate Epidemic and Child Protection (2016).

141. The overprescribing of opioids for chronic pain caused by Defendants' deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in Ohio who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome. These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts. Babies with NAS typically require extensive hospital stays as they withdraw. In 2013, the average inpatient stay and bill for NAS infants was four times longer and four times higher than for other Ohio infants.[38] Newborns with NAS spent approximately 26,000 days in Ohio hospitals in 2014 with health care costs totaling $105 million.[39] In 2014, 1,875 babies with NAS were admitted to inpatient settings in Ohio – an average of more than 5 per day. In April 2016, it was reported by the Ohio Perinatal Quality Collaborative that 4,000 babies had been treated for NAS at Ohio hospitals during the preceding 18 month period.[40]

[38] Ohio Department of Health (2013). Neonatal abstinence syndrome (NAS) in Ohio, 2004- 2013, preliminary report. Retrieved from http://www.healthy.ohio.gov/~/media/HealthyOhio/ASSETS/Files/injury%20prevention/NAS%20Summary%20Report%200317b.pdf.

[39] Ohio Maternal Opiate Medical Supports (M.O.M.S.) Project, 2016 Infant Mortality Summit.

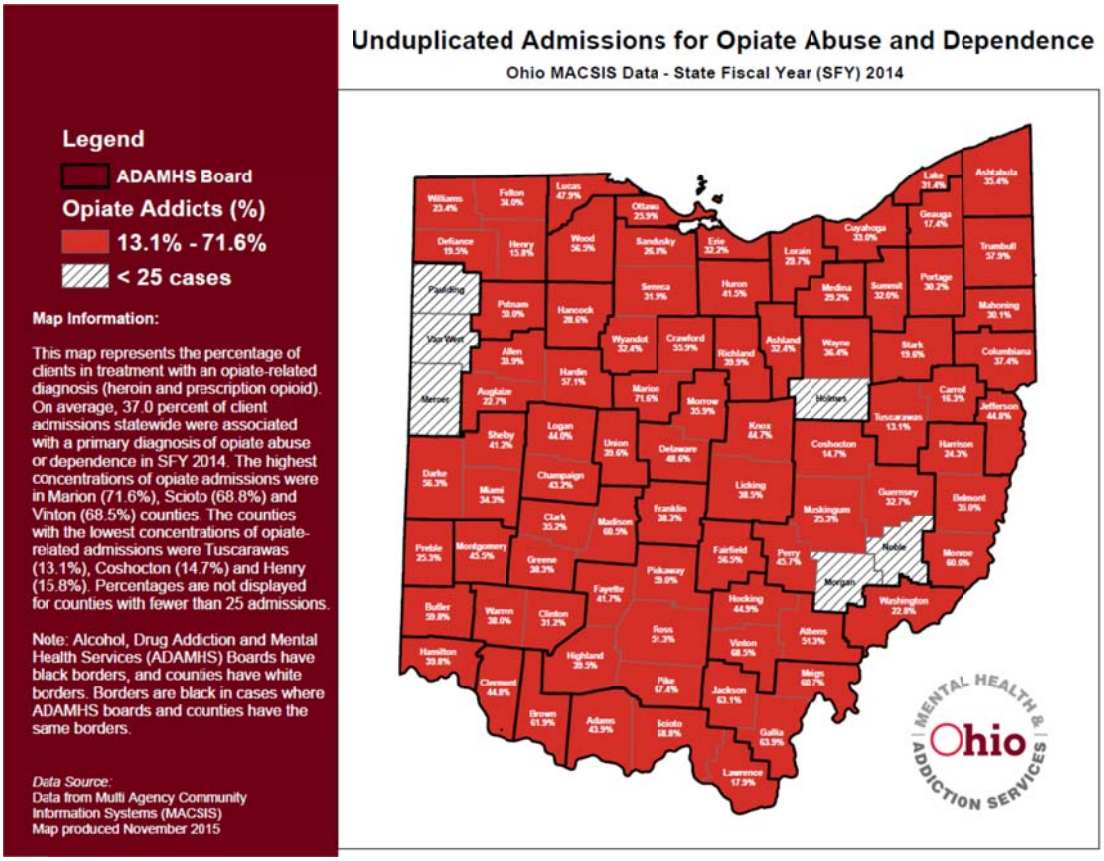
[40] Christopher Evans, Cleveland.com, *Addiction city: Ohio's opiate addicts would make the fifth largest city in the state*, http://www.cleveland.com/metro/index.ssf/2016/04/--_the_heroin_crisis_in_ohio.html (last accessed May 12, 2017).



142. Opioid addiction is now the primary reason that Ohioans seek substance abuse treatment. In 2014, 37 percent of admissions for drug abuse were associated with a primary diagnosis of opiate abuse or dependence.[41] In 2016, there were 200,000 opioid addicts in the state – roughly equivalent to the entire population of the city of Akron.[42]

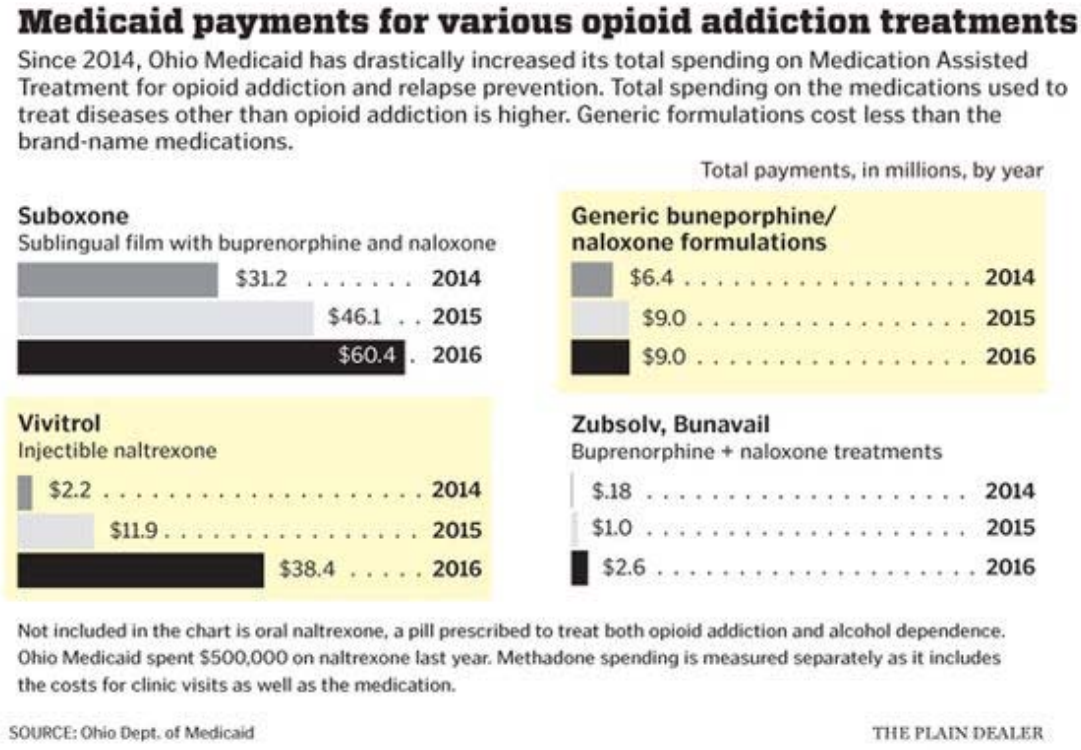
[41] Unduplicated Admission for Opiate Abuse and Dependence, Ohio MACSIS Data State Fiscal Year 2014.

[42] Ohio Automated RX Reporting System, 2016 Annual Report.



143. Since 2014, the state has repeatedly increased spending on Medication Assisted Treatments ("MATs") to address opioid addiction. Expenditures on MATs have more than doubled from $40 million in 2014 to over $110 million in 2016. This expense is in addition to treatment and counseling services which cost the state another $462 million between 2014 and 2016.[43]

[43] Rachel Dissell, *Ohio's spending on opioid addiction treatment drugs Vivitrol and Suboxone spikes, spurs debate on what treatments work*, Cleveland.com (Apr. 30, 2017).



144. The number of emergency medical services ("EMS") runs for suspected opioid-related overdose has also increased. Between 2003 and 2012, Naloxone, a drug used to reverse opiate-induced overdoses, was administered approximately 74,000 times by Ohio EMS personnel *alone*. The number of EMS Naloxone administrations per year grew from 4,010 in 2003 to 10,589 in 2012 – a 164 percent increase. This means that, on average, there were 11 emergency administrations of Naloxone per day in 2003 and 29 per day in 2012.[44] In 2015, that figure went up even more, with Ohio EMS personnel administering a total of 19,782 doses.[45]

[44] Massatti, R. (2013, November), *Naloxone (Narcan) Administration in Ohio, 2003-2012*. Columbus, OH: Ohio Department of Mental Health and Addiction Services.

[45] Ohio Department of Health News Release, *Illicit Fentanyl Continues to Fuel Increase in Drug Overdose Deaths in Ohio* (Aug. 25, 2016).

145. Defendants' creation, through false and deceptive advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed communities throughout Ohio. Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.[46]

146. Law enforcement agencies have increasingly associated prescription drug abuse with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including: doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment. The opioid epidemic has prompted a growing trend of crimes against pharmacies including robbery and burglary. In fact, a 2005 study by The Center on Addiction and Substance Abuse at Columbia University revealed that, by that time, 20.9% of pharmacies nationwide had stopped stocking certain medications such as OxyContin and Percocet, in order to protect themselves from robbery. This ongoing diversion of prescription narcotics creates a lucrative marketplace. For example, the Ohio Substance Abuse Monitoring Network recently released their report on "Drug Abuse Trends in the Cleveland Region." The report is associated with the Ohio Department of Mental Health and Addiction Services, and was "based upon qualitative data collected via focus groups interviews" of "active and recovering drug users recruited from alcohol and other drug

[46] Nathaniel P. Katz, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, Am. J. Managed Care (Apr. 19 2013), at 5 ("The most common source of abused [opioids] is, directly or indirectly, by prescription."), *available at* http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers.

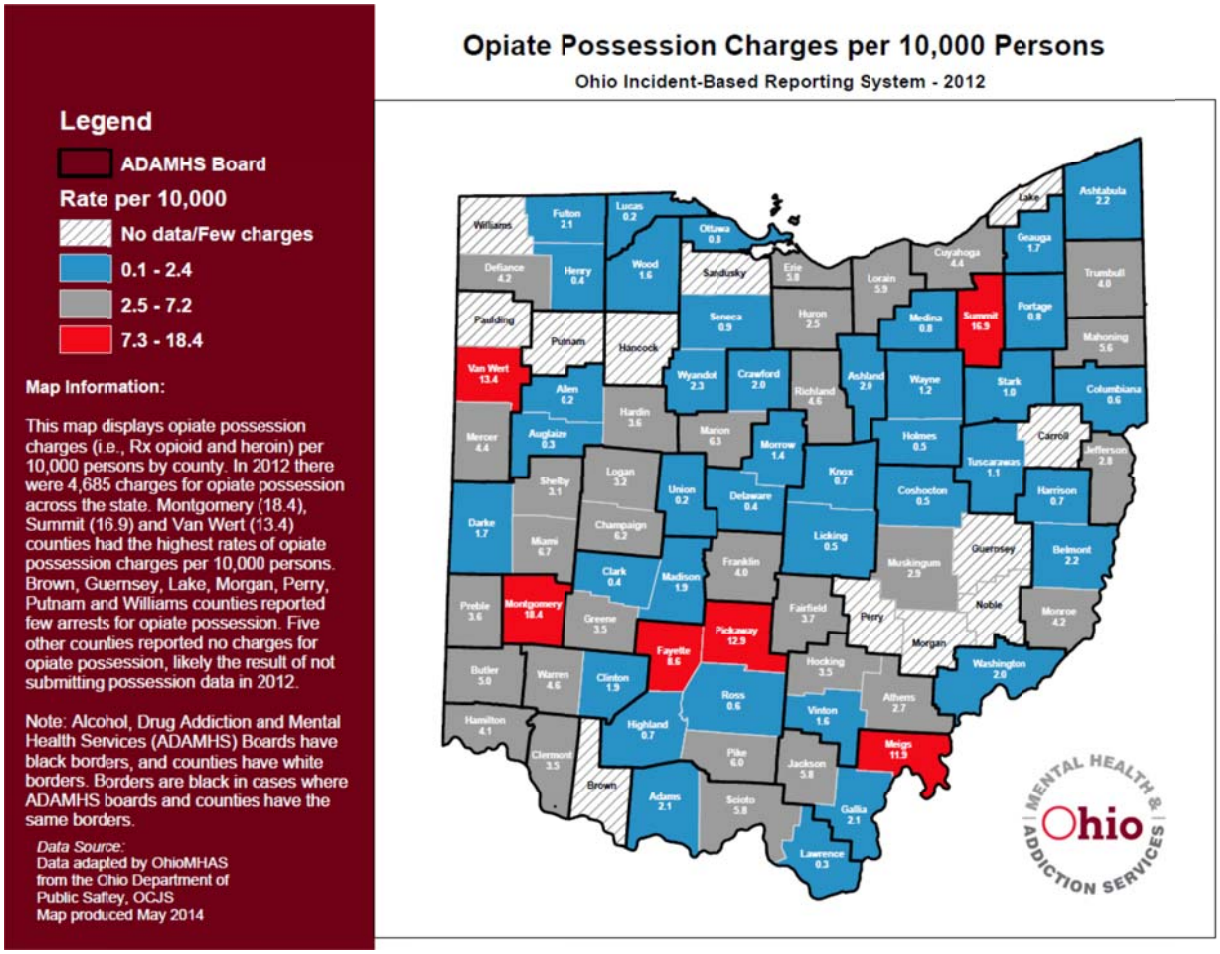
treatment programs in Cuyahoga, Geauga and Lake Counties." That report, which observed that "prescription opioids remain highly available in the region," found the following street prices for prescription opioids:

Prescription Opioids	Current Street Prices for Prescription Opioids
Dilaudid®	$20 for 8 mg
fentanyl	$150 per patch (unspecified dose)
methadone	$40 for 90 pills (unspecified dose) $60 for 30-day liquid supply (unspecified dose)
Opana®	$2 per mg
OxyContin®	$100 for 80 mg
Percocet®	$7 for 5 mg $10 for 7.5 mg $14 for 10 mg
Vicodin®	$2-4 for 5 mg $7-8 for 10 mg

Thus, for example, a bottle of 100 80-mg tablets of OxyContin would have a street value of anywhere between $1,600 and $4,000.

147. The number of criminal possession charges for opioid drugs has also increased. In 2014, there were 5,562 charges for opiate possession across the state. That number rose from 5,115 in 2013 and 4,685 in 2012.[47]

[47] Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010.



148. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription opioids. A study by the Ohio Substance Abuse Monitoring Network found that, "young new heroin abusers seeking treatment reported OxyContin abuse prior to becoming addicted to heroin."[48] In 2014 and 2015, Ohio recorded the largest number of heroin-related fatal overdoses of any state – with 1 in every 9 deaths in the United States occurring in Ohio.[49] Heroin-related deaths accounted for 1,424 unintentional drug overdose

[48] Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010.

[49] The Henry J. Kaiser Family Foundation Overdose Deaths, 2014 and 2015.

deaths in 2015, an increase from 1,196 in 2014. In 2015, heroin was involved in 46.7% of all overdose deaths in the state of Ohio.[50]

149. The costs and consequences of opioid addiction are staggering. Prescription opioid misuse, abuse and overdose have an enormous impact on the health and safety of individuals as well as communities at large, as the consequences of this epidemic reach far beyond the individual who is addicted. Some of the repercussions for individuals include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration. This results in instability in communities often already in economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers and law enforcement.[51] In addition, the resulting costs of unintentional drug overdose are shocking; unintentional fatal drug overdoses cost Ohioans $2 billion in 2012 while non-fatal hospital admitted drug poisonings cost an additional $39.1 million. In 2012, the total cost to the state averaged $5.4 million *per day* in medical and work loss expenses.[52]

150. Defendants knew and should have known about these harms that their deceptive marketing has caused. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew – and, indeed, intended – that their

[50] 2015 Ohio Drug Overdose Data: General Findings.

[51] Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010.

[52] Ohio Department of Health, Prevalence and Trends in Unintentional Drug Overdose.

misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain.

151. Defendants' actions are not permitted nor excused by the fact that their drug labels (with the exception of the Actiq/Fentora labels) may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

152. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

F. The Defendants' Unlawful Opioid Promotion And Scheme Has Caused Substantial Economic Injury To State Agencies

1. Excessive opioid prescriptions paid for by the Department of Medicaid and the Bureau of Workers' Compensation

153. Between 2006 and 2016, the Department of Medicaid spent nearly $175 million on Defendants' opioids. Many of these prescriptions were for chronic pain, and the State would not have paid for them had Defendants told the truth about the risks and benefits of their drugs.

154. Similarly, Ohio's Bureau of Workers' Compensation ("BWC"), the exclusive provider of workers' compensation insurance to Ohio's employers, paid for excessive opioid prescriptions. By way of example, BWC paid for 479,967 opioid prescriptions in 2011; 378,527

prescriptions in 2013, and 248,712 prescriptions in 2016. But for Defendants' promotion of opioid use for chronic pain, BWC would not have paid for many of these prescriptions.

155. Nationally, the amount of such prescriptions paid by workers' compensation programs is monumental. A study by the National Council on Compensation Insurance ("NCCI") concluded that, in 2011, approximately 38% of pharmacy costs in workers' compensation are for opioids and opioid combinations, amounting to approximately $1.4 billion.

2. Associated treatment costs paid for by the Department of Medicaid and the Bureau of Workers' Compensation

156. There have been monumental costs associated with the treatment of patients addicted to prescription opioids as well. Statewide, payments for drugs designed to treat opiate addiction, Medication Assisted Treatments ("MATs"), have more than doubled – from $40 million to more than $110 million – since 2014 when Medicaid coverage expanded to cover an additional 700,000 uninsured, low-income Ohioans.[53] Treatment and counseling services cost another $462 million in public money from 2014 to 2016.[54] Courts, jails and prisons received at least $16 million more in state grants to cover the costs of MATs, treatment and case management for the uninsured.[55]

157. The BWC also paid costs associated with opioids, including treatment related to any adverse outcomes from chronic opioid therapy, such as addiction treatment. Even today, opiate addictions afflict nearly one in six BWC lost-time claimants.[56]

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[53] Rachel Dissell, *Ohio's spending on opioid addiction treatment drugs Vivitrol and Suboxone spikes, spurs debate on what treatment works*, PLAIN DEALER (Apr. 30, 2017).

[54] *Id.*

[55] *Id.*

[56] Ohio Bureau of Workers' Compensation, Fiscal Year 2016 Report, at 39.

158. Nationally, claims involving workers who take opioids are almost four times more likely to reach costs of over $100,000 than claims involving workers without opioids because opioid patients suffer greater side effects and are slower to return to work.[57] Even adjusting for injury severity and self-reported pain score, receiving an opioid for more than seven days and receiving more than one opioid prescription increased the risk that a patient will be on work disability one year later.[58] A prescription for opioids as the first treatment for a workplace injury doubled the average length of the claim.[59]

G. Defendants' Fraudulent Marketing Has Led To Record Profits.

159. While the use of opioids has taken an enormous toll on the State of Ohio and its residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described above.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

PUBLIC NUISANCE
OHIO PRODUCT LIABILITY ACT ("PLA"), R.C. 2307.71, *ET SEQ.*

160. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

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[57] Jeffrey A. White, *et al.*, *The Effect of Opioid Use on Workers' Compensation Claim Cost in the State of Michigan*, 54(8) J. of Occupational & Environ. Med. 948-953 (2012).

[58] Gary M. Franklin, *et al.*, *Early Opioid Prescription and Subsequent Disability Among Workers with Back Injuries: The Disability Risk Identification Study Cohort*, 33(2) *Spine* 199-204 (2008).

[59] Dongchun Wang, *et al.*, *Longer-Term Use of Opioids*, Workers Comp. Res. Inst. (Oct. 2012).

161. This action is brought by the State under the PLA to seek compensatory damages from Defendants for death, physical injury to person, emotional distress or physical damage to property. Both the Department of Medicaid and BWC paid such costs for addiction treatment, MATs and other services necessary for the treatment of people addicted to prescription opioids, including the treatment of babies born afflicted with Neonatal Abstinence Syndrome.

162. Defendants, individually and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is harmful to the health of Ohioans or interferes with the comfortable enjoyment of life in violation of Ohio law.

163. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid use resulting from Defendants' marketing efforts have caused harm to the community that includes, but is not limited to:

a. Upwards of 30% of all adults have used them. These high rates of use have led to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

b. Children too have been harmed by opioids. They have been exposed to medications prescribed to family members or others, resulting in injury, addiction, and death. Easy access to prescription opioids has made opioids a recreational drug of choice among Ohio teenagers; opioid use among teenagers is only outpaced by marijuana use. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. Ohioans who have never taken opioids also have suffered the costs of Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

d. More broadly, opioid use and misuse have driven Ohioans' health care costs higher.

e. Employers have lost the value of productive and healthy employees who suffered from adverse consequences from opioid use.

f. Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created both ends of a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them.

g. This demand also has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process.

h. The diversion of opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids has increased the demands on emergency services and law enforcement in the State.

i. All of this has caused significant harm to the community – in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken families and homes.

j. These harms have taxed the human, medical, public health, law enforcement, and financial resources of the State.

k. Defendants' interference with the comfortable enjoyment of life of a substantial number of people is entirely unreasonable because there is little social utility to opioid use and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

164. Defendants knew or should have known that their promotion of opioid use would create a public nuisance.

a. Defendants have engaged in massive production, promotion, and distribution of opioids for use by the citizens of the State.

b. Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management.

c. Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs.

d. Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community would suffer as a result.

165. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used. Defendants' actions were, at the least, a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain. Without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

166. The health and safety of the citizens of the State, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to the State's citizens and residents.

167. Defendants' conduct has affected and continues to affect a considerable number of people within the State and is likely to continue to cause significant harm to chronic pain patients who take opioids, their families, and the community at large.

SECOND CAUSE OF ACTION

PUBLIC NUISANCE
OHIO COMMON LAW

168. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

169. This action is brought by the State under Ohio common law to seek damages and abate the public nuisance created by the Defendants. This Cause of Action does not seek compensatory damages for death, physical injury to person, emotional distress, or physical damage to property.

170. Defendants, individually and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is harmful to the health of Ohioans or interferes with the comfortable enjoyment of life in violation of Ohio law.

171. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid use resulting from Defendants' marketing efforts have caused harm to the community that includes, but is not limited to:

a. Upwards of 30% of all adults have used them. These high rates of use have led to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

b. Children too have been harmed by opioids. They have been exposed to medications prescribed to family members or others, resulting in injury, addiction, and death. Easy access to prescription opioids has made opioids a recreational drug of choice among Ohio teenagers; opioid use among teenagers is only outpaced by marijuana use. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. Ohioans who have never taken opioids also have suffered the costs of Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

d. More broadly, opioid use and misuse have driven Ohioans' health care costs higher.

e. Employers have lost the value of productive and healthy employees who suffered from adverse consequences from opioid use.

f. Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created both ends of a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them.

g. This demand also has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process.

h. The diversion of opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids has increased the demands on emergency services and law enforcement in the State.

i. All of this has caused significant harm to the community – in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken families and homes.

j. These harms have taxed the human, medical, public health, law enforcement, and financial resources of the State.

k. Defendants' interference with the comfortable enjoyment of life of a substantial number of people is entirely unreasonable because there is little social utility to opioid use and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

172. Defendants knew or should have known that their promotion of opioid use would create a public nuisance.

a. Defendants have engaged in massive production, promotion, and distribution of opioids for use by the citizens of the State.

b. Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management.

c. Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs.

d. Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community would suffer as a result.

173. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used. Defendants' actions were, at the least, a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain. Without Defendants' actions, opioid use would not have become so widespread,

and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

174. The health and safety of the citizens of the State, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to the State's citizens and residents.

175. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further reoccurrence of such harm and inconvenience can be prevented.

176. Defendants' conduct has affected and continues to affect a considerable number of people within the State is likely to continue to cause significant harm to chronic pain patients who take opioids, their families, and the community at large.

177. Each Defendant created or assisted in the creation of the epidemic of opioid use and injury, and each Defendant is jointly and severally liable for abating it.

THIRD CAUSE OF ACTION

OHIO CONSUMER SALES PRACTICES ACT ("CSPA") R.C. 1345.02 AND 1345.03

178. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

179. This Cause of Action is brought in the public interest under the Ohio Consumer Sales Practices Act ("CSPA"), R.C. 1345.01, *et seq.*, and seeks a declaratory judgment that Defendants have violated the CSPA, an injunction enjoining Defendants' misrepresentations described in this Complaint, restitution to Ohio consumers who paid for opioid prescriptions for chronic pain and therefore have been damaged by Defendants' conduct, and civil penalties. Between 2006 and 2016, Ohio consumers spent over $200 million on Defendants' opioids.

180. The CSPA prohibits, in connection with consumer transactions, unfair, deceptive or unconscionable consumer sales practices that mislead consumers about the nature of the product they are receiving. Specifically, the CSPA prohibits sellers from representing: that the subject of a consumer transaction has sponsorship, approval, performance characteristics, accessories, uses, or benefits that it does not have. R.C. 1345.02(B)(1).

181. In addition, Section 109:4-3-10 of the Ohio Administrative Code, interpreting the CSPA, makes it a deceptive act or practice for a supplier, in connection with a consumer transaction to "[m]ake any representations, claims, or assertions of fact, whether orally or in writing, which would cause a reasonable consumer to believe such statements are true, unless, at the time such representations, claims or assertions are made, the supplier possesses or relies upon a reasonable basis in fact such as factual, objective, quantifiable, clinical or scientific data or other competent or reliable evidence which substantiates such representations, claims, or assertions of fact."

182. Further, under R.C. 1345.07(A)(3)(c), the following acts are deemed to be deceptive pursuant to cases located within the Attorney General's Public Inspection File ("PIF"):

- Making any express or implied statement in connection with the marketing or advertisement of any product that is false, or has the capacity, tendency or effect of deceiving or misleading consumers; or omitting any material information such that the express or implied statement deceives or tends to deceive consumers. *State of Ohio ex rel. Rogers v. Airborne Health, Inc.*, Case No. 08-CVH-1217848 (Ct. Cmmn. Pleas, Franklin Cty).

- Making any representation, in connection with the marketing or advertising of a product, about research that has been performed, including but not limited to any representation that a product has been clinically tested unless at the time the claim is made, competent and reliable scientific evidence exists substantiating such claim. *Airborne Health*.

- Making, in connection with the marketing or advertising of a product . . . any statements or representations concerning a product that materially contradict or conflict with any other statements or representations the Defendants made about

such Product and rend such statements or representations misleading and/or deceptive. *Airborne Health*.

- Making, or causing to be made, any written or oral claim that is false, misleading or deceptive. *State of Ohio ex rel. Michael DeWine v. Amgen Inc.*, Case No. 15CV7216 (Ct. Cmmn. Pleas, Franklin Cty).

- Representing that any product has any sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have. *Amgen Inc.*

- Representing that any product has any sponsorship, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have. *Amgen, Inc.*

- Making in a promotional context an express or implied representation, not approved or permitted for use in the labeling or under the FDCA, that a product is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by competent and reliable scientific evidence, whether or not such express or implied representation is made by comparison with another drug or treatment, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, a quotation, or other reference. *Amgen Inc.*

- Presenting information from a study in a way that implies that the study represents larger or more general experience with a product than it actually does. *Amgen Inc.*

- Misleadingly presenting favorable information or conclusion(s) from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusion(s) for information that may be material to an HCP prescribing decision when presenting information about a clinical study regarding a product. *Amgen Inc.*

- Making, or causing to be made, any written or oral claim, directly or by promotional speakers, that is false, misleading, or deceptive regarding any FDA-approved product, including, but not limited to, any false, misleading, or deceptive claim when comparing the efficacy or safety of two products. *State of Ohio ex rel. Michael DeWine v. Pfizer Inc.*, Case No. 12 CV 15188 (Ct. Cmmn. Pleas, Franklin Cty.).

- Making any claim, directly or by promotional speakers, comparing the safety or efficacy of a product to another product when they claim is not supported by substantial evidence. *Pfizer Inc.*

- Making any claim, directly or by promotional speakers, that contradicts or minimizes a precaution, warning, or adverse reaction that is described in product labeling. *Pfizer Inc.*

183. As alleged herein, each Defendant, at all times relevant to this Complaint, violated the CSPA by making deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

184. Defendant Purdue made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to Ohio consumers that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Exclusively disseminating misleading statements in education materials to Ohio hospital doctors and staff while purportedly educating them on new pain standards;

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing; and

- Withholding from Ohio law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

185. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high-risk patients;
- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing.

186. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

- Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing.

187. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

- Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

- Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing and speakers bureau events, when such uses are unapproved and unsafe; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing and speakers bureau events.

188. Defendant Actavis made and/or disseminated deceptive statements, including, but not limited to, the following:

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing;

- Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

- Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

189. These deceptive representations and concealments were reasonably calculated to deceive the State and Ohio consumers, were made with the intent to deceive the State and Ohio

consumers, and did in fact deceive the State and Ohio consumers, who paid for prescription opioids for chronic pain.

190. As described more specifically above, Defendants' representations and concealments constitute a course of conduct which continues to this day.

191. But for these deceptive representations and concealments of material fact, Ohio consumers would not have incurred millions of dollars in overpayments.

192. As a direct and proximate cause of Defendants' deceptive conduct, Ohio consumers have been injured in an amount to be determined at trial.

FOURTH CAUSE OF ACTION

MEDICAID FRAUD
R.C. 2307.60 (FOR VIOLATION OF R.C. 2913.40)

193. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

194. Section 2913.40(B) of the Ohio Revised Code provides that "[n]o person shall knowingly make or cause to be made a false or misleading statement or representation for use in obtaining reimbursement from the medicaid program," and makes the commission of Medicaid fraud a crime in the State of Ohio.

195. Section 2307.60(A)(1) of the Ohio Revised Code provides that anyone injured in person or property by a criminal act may recover full damages in a civil action.

196. Defendants' practices, as described in the Complaint, violated Section 2913.40(B) of the Ohio code. Defendants, through their deceptive marketing of opioids for chronic pain, made or caused to be made false or fraudulent statements for use in obtaining reimbursement from the Department of Medicaid.

197. Defendants knew, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and were made for the purpose of getting the Department of Medicaid to pay for opioids for long-term treatment of chronic pain. In addition, Defendants knew that their marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

198. Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic pain that were paid for by the Department of Medicaid.

199. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Department of Medicaid to approve and pay such false claims.

200. The Department of Medicaid, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, paid – and continues to pay for reasons explained above – claims that would not be paid but for Defendants' illegal business practices.

201. By reason of Defendants' unlawful acts, the Department of Medicaid has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Between 2006 and 2016, the Department of Medicaid spent nearly $175 million on Defendants' opioids. The Department of Medicaid also suffered additional damages for the costs of providing services, such as addiction treatment, related to the long-term use of opioids to treat chronic pain.

202. Each Defendant is responsible for the claims submitted and the amount the Department of Medicaid spent on its opioids.

203. Because Defendants' unbranded marketing caused the doctors to prescribe and the Department of Medicaid to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Defendants caused and are responsible for those costs and claims, as well.

FIFTH CAUSE OF ACTION

COMMON LAW FRAUD

204. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

205. As alleged herein, Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

206. Defendant Purdue made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to Ohio consumers that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Exclusively disseminating misleading statements in education materials to Ohio hospital doctors and staff while purportedly educating them on new pain standards;

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing; and

- Withholding from Ohio law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber

education materials and advertisements and CMEs they knew would reach these same prescribers.

207. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high-risk patients;
- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing.

208. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

- Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing.

209. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

- Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

- Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing and speakers bureau events, when such uses are unapproved and unsafe; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing and speakers bureau events.

210. Defendant Actavis made and/or disseminated deceptive statements, including, but not limited to, the following:

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing;

- Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

- Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

211. These false representations and concealments were reasonably calculated to deceive the State and the physicians who submitted prescriptions for payment to the State, were made with the intent to deceive, and did in fact deceive the State and the physicians who submitted prescriptions for payment to the State, which paid for prescription opioids for chronic pain.

212. But for these false representations and concealments of material fact, the State and its agencies would not have incurred millions of dollars in overpayments.

213. The State and the physicians who submitted opioid prescriptions for payment to the State reasonably relied on these false representations and concealments of material fact.

214. As a direct and proximate cause of Defendants' fraudulent conduct, the State has been injured.

SIXTH CAUSE OF ACTION

OHIO CORRUPT PRACTICES ACT ("OCPA")

R.C. 2923.31, *ET SEQ.*
(AGAINST PURDUE, JANSSEN, CEPHALON AND ENDO)

215. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

216. This claim is brought by the State against Defendants Purdue, Janssen, Cephalon and Endo for actual damages, treble damages, and equitable relief under R.C. 2923.34 for violations of R.C. 2923.31, *et seq.*, and, throughout this Cause of Action only, Defendants refers only to these entities.

217. The Defendants are "persons" within the meaning of R.C. 2923.31(G) who conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of R.C. 2923.31.

218. The State is a "person," as that term is defined in R.C. 2923.31, who was injured in its business or property as a result of Defendants' wrongful conduct. Specifically, the State, including the Department of Medicaid and BWC, paid for more prescriptions for opioids for chronic pain than it would have paid had Defendants, directly or through KOLs or Front Groups, told the truth about the risks and benefits about their drugs.

A. The Opioids Marketing Enterprise

219. Defendants formed an association-in-fact enterprise – sometimes referred to in this Complaint as the Opioids Marketing Enterprise. The Opioids Marketing Enterprise consists of (a) Defendants, including their employees and agents; (b) the Front Groups, including their employees and agents; and (c) the KOLs.

220. The Opioids Marketing Enterprise is an ongoing and continuing business organization that created and maintained systematic links for a common purpose: to ensure the prescription of opioids for chronic pain.

221. To accomplish this purpose, the Opioids Marketing Enterprise periodically and systematically misrepresented – either affirmatively or through half-truths and omissions – to the general public, the State, and Ohio consumers, the risks and benefits of using opioids for chronic pain. The Opioids Marketing Enterprise concealed from the public, the State, and Ohio consumers, the serious risks and lack of corresponding benefits of using opioids for chronic pain. By making those representations, the Opioids Marketing Enterprise ensured that a larger number of opioid prescriptions would be written and filled for chronic pain. This translated into higher sales (and therefore profits) for Defendants.

222. The persons engaged in the Opioids Marketing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Defendants. There is regular communication between Defendants, Front Groups and KOLs, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Defendants, Front Groups and KOLs share information regarding overcoming objections to the use of opioids for chronic pain. Defendants, the Front Groups and KOLs functioned as a continuing unit for the purposes of implementing the Opioids Marketing Scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

223. At all relevant times, Front Groups were aware of Defendants' conduct, were a knowing and willing participant in that conduct, and reaped benefits from that conduct. Each Front Groups also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of the State and Ohio consumers. But for the Opioids Marketing Enterprise's unlawful fraud, Front Groups would have had the incentive to disclose the deceit by Defendants to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioids Marketing Enterprise's scheme, and reaped substantial benefits.

224. At all relevant times, KOLs were aware of Defendants' conduct, were knowing and willing participants in that conduct, and reaped profits from that conduct. Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of

consumers and the State. But for the Opioids Marketing Enterprise's unlawful fraud, KOLs would have been incentivized to disclose the deceit, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs perpetuated the Opioids Marketing Enterprise's scheme, and reaped substantial benefits.

225. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged communities in Ohio and throughout the United States, the Front Groups and KOLs did not challenge Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioids Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

226. The Front Groups and KOLs participated in the conduct of the Opioids Marketing Enterprise, sharing the common purpose of marketing opioids for chronic pain and, through a pattern of racketeering activity, which includes multiple instances of mail fraud, and multiple instances of wire fraud, they knowingly made material misstatements or omissions to Ohio physicians, consumers, the State and the general public in furtherance of the fraudulent scheme, including that:

a. it was rare, or there was a low risk, that Defendants' opioids could lead to addiction;[60]

b. the signs of addiction were actually signs of undertreated pain that should be treated by more opioids;[61]

c. opioid dependence could be easily addressed by tapering and that opioid withdrawal is not difficult;[62]

[60] American Pain Foundation's *Treatment Options: A Guide for People Living in Pain* (2007) (sponsored by Cephalon and Purdue) (still available online); American Pain Foundation's *A Policymaker's Guide to Understanding Pain and Its Management* (sponsored by Purdue) (still available online).

[61] National Initiative on Pain Control 2009 CME program, *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia* (sponsored by Endo).

d. doctors could increase opioid dosages indefinitely without added risk;[63]

e. long-term opioid use improved patients' function and quality of life;[64]

f. Purdue's OxyContin provided 12 hours of continuous pain relief;[65] and

g. the extent to which the Opioids Marketing Scheme caused the State and Ohio consumers to pay for excessive opioid prescriptions, and to incur costs associated with abating the opioid epidemic caused by the Enterprise.

227. Defendants alone could not have accomplished the purpose of the Opioids Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than Defendants themselves. Without these misrepresentations, the Opioids Marketing Enterprise could not have achieved its common purpose.

228. The impacts of the Opioids Marketing Enterprise's scheme are still in place – *i.e.*, the opioids continue to be prescribed and used for chronic pain throughout the State of Ohio, and the epidemic continues to consume the resources of Ohio's health care and law enforcement systems.

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[62] American Pain Foundation's *A Policymaker's Guide to Understanding Pain and Its Management* (sponsored by Purdue) (still available online).

[63] American Pain Foundation's *Treatment Options: A Guide for People Living in Pain* (2007) (sponsored by Cephalon and Purdue) (still available online); Endo pamphlet edited by KOL: *Understanding Your Pain: Taking Oral Opioid Analgesics*; American Pain Foundation's *A Policymaker's Guide to Understanding Pain and Its Management* (sponsored by Purdue) (still available online).

[64] *Responsible Opioid Prescribing* (sponsored by Endo, Cephalon and Purdue) (remains for sale online); American Pain Foundation's *Treatment Options: A Guide for People Living in Pain* (2007) (sponsored by Cephalon and Purdue) (still available online); CME entitled *Persistent Pain in the Older Patient* (sponsored by Endo).

[65] American Pain Foundation.

229. The foregoing evidences that Defendants, the Front Groups and the KOLs were each willing participants in the Opioids Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

B. Conduct of the Opioids Marketing Enterprise

230. During time period described in this Complaint, from approximately 2006 to the present, Defendants exerted control over the Opioids Marketing Enterprise and participated in the operation or management of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

a. Defendants created a body of deceptive and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;

b. Defendants selected, cultivated, promoted and paid the KOLs based solely on their willingness to communicate and distribute Defendants' messages about the use of opioids for chronic pain;

c. Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

d. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, typically over meals or at conferences;

e. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

f. Defendants sponsored CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

g. Defendants developed and disseminated pro-opioid treatment guidelines;

h. Defendants encouraged Front Groups to disseminate their pro-opioid messages to groups targeted by Defendants, such as veterans and the elderly, and then funded that distribution;

i. Defendants concealed their relationship to and control of Front Groups and KOLs from the State and the public at large; and

j. Defendants intended that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

231. The scheme had a hierarchical decision-making structure that was headed by Defendants. Defendants controlled representations made about their drugs, and doled out funds to PBMs and payments to KOLs to ensure the representations made were consistent with Defendants' messaging nationwide and throughout the State of Ohio. Front Groups were dependent on Defendants for their financial structure, and KOLs were professionally dependent on Defendants for the development and promotion of their careers.

232. The Front Groups also participated in the conduct of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages themselves;

b. The Front Groups distribute through the U.S. Mail and interstate wire facilities promotional and other materials which claimed that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and

c. The Front Groups concealed their connections to Defendants.

233. The KOLs also participated in the conduct of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages themselves;

b. The KOLs distributed through the U.S. Mail and interstate wire facilities promotional and other materials which claimed that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and

c. The KOLs concealed their connections to and sponsorship by Defendants.

234. The scheme devised and implemented by Defendants, as well as other members of the Opioids Marketing Enterprise, amounted to a common course of conduct intended to encourage the prescribing and use of opioids for chronic pain and thereby secure payment for prescriptions of Defendants' opioids by Ohio patients and the State, including the Department of Medicaid and Ohio BWC. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

C. Pattern of Racketeering Activity

235. Defendants conducted and participated in the conduct of the affairs of the Opioids Marketing Enterprise through a pattern of racketeering activity as defined in R.C. 2923.31(I)(2), which constitutes Corrupt Activity under R.C. 2923.31(I)(1). The pattern of racketeering activity by the Opioids Marketing Enterprise likely involved thousands of separate instances of use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioids Marketing Enterprise. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which Defendants, the Front Groups and the KOLs defrauded and intended to defraud Ohio consumers, the State, and other intended victims.

236. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Ohio consumers and the State. Defendants, the Front Groups and the KOLs calculated and intentionally crafted the opioids marketing scheme to

ensure their own profits remained high, without regard to the effect such behavior had on Ohio consumers and the State. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding Defendants' products.

237. By intentionally misrepresenting the risks and benefits of using opioids for chronic pain, and then subsequently failing to disclose such practices to Ohio consumers or the State, Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

238. Defendants', the Front Groups' and the KOLs' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive the State and Ohio consumers. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including the State and Ohio consumers. Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its Opioids Marketing Enterprise.

239. The pattern of racketeering activity alleged herein and the Opioids Marketing Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the Opioids Marketing Enterprise.

240. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

241. Many of the precise dates of the Opioids Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to Defendants', the Front Groups' and the KOLs' books and records. Indeed, an essential part of the successful operation of the Opioids Marketing Enterprise alleged herein depended upon secrecy. However, the State can generally describe the occasions on which the predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the scheme, and do so below.

242. Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, including, *inter alia*:

a. Marketing materials about Defendants' opioids, and their risks and benefits, which Defendants sent to health care providers located across the country and the State;

b. Written representations and telephone calls between Defendants and Front Groups regarding representations about Defendants' opioids, or the use of opioids for chronic pain generally;

c. Written representations and telephone calls between Defendants and KOLs regarding Defendants' opioids, or the use of opioids for chronic pain generally;

d. Hundreds of e-mails between Defendants and the Front Groups agreeing to or effectuating the implementation of the opioids marketing scheme;

e. Hundreds of e-mails between Defendants and KOLs agreeing to or effectuating the implementation of the opioids marketing scheme;

f. Hundreds of communications between the Front Groups and publications, groups drafting treatment guidelines and the media effectuating the implementation of the opioids marketing scheme;

g. Hundreds of communications between the KOLs and publications, groups drafting treatment guidelines and the media effectuating the implementation of the opioids marketing scheme;

h. Written and oral communications directed to State agencies and private insurers throughout the State that fraudulently misrepresented the risks of benefits of using opioids for chronic pain; and

i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities – the wrongful proceeds of the scheme.

243. In addition to the above-referenced predicate acts, it was foreseeable to Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

D. Damages Caused by Defendants' Fraud

244. Defendants' violations of law and their pattern of racketeering activity have directly and proximately caused the State, and specifically the Department of Medicaid and BWC, as well as consumers within the State, to be injured in their business or property because they have paid for opioid prescriptions for chronic pain for which they would not otherwise have paid.

245. The State's injuries, and those of Ohio consumers, were proximately caused by Defendants' racketeering activity. But for the misstatements made by Defendants, the Front Groups and the KOLs and the scheme employed by the Opioids Marketing Enterprise, the State and Ohio consumers would not have paid for opioid prescriptions for chronic pain.

246. The State's injuries were directly caused by Defendants' racketeering activity. Although the misstatements made by the Front Groups and the KOLs in furtherance of the Opioids Marketing Enterprise were directed primarily to health care providers, those providers did not have to make payments for opioids prescribed for chronic pain. Therefore, Ohio health care providers did not suffer the same injuries alleged in this Complaint.

247. The State and its citizens were most directly harmed by the fraud, and there is no other Plaintiff or class of plaintiffs better situated to seek a remedy for the economic harms to consumers from Defendants' fraudulent scheme.

248. By virtue of these violations of R.C. 2923.34, Defendants are liable to the State for three times the damages Plaintiff has sustained, plus the cost of this suit, including reasonable attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays:

A. That the acts alleged herein be adjudged and decreed to be unlawful in violation of State statutory and common law and that the Court enter a judgment declaring them to be so;

B. That Defendants be enjoined from, directly or indirectly through KOLs, Front Groups or other third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, and from continuing to violate Ohio law;

C. That Plaintiff recover all measures of damages allowable under the State statutes identified herein and the common law, and that judgment be entered against Defendants in favor of Plaintiff;

D. That Plaintiff recover restitution on behalf of Ohio consumers who paid for opioids for chronic pain;

E. That Plaintiff receive an award of civil penalties for Defendants' deceptive acts as determined in cases located within the Attorney General's Public Inspection File ("PIF");

F. That Plaintiff recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorneys' fees as provided by law;

G. That Defendants be ordered to abate the public nuisance that they created in in violation of Ohio common law;

H. That Defendants be ordered to pay punitive and treble damages as provided by law; and

I. That the Court order such other and further relief as the Court deems just, necessary and appropriate.

DATED this 31st day of May, 2017.

JURY DEMAND ENDORSEMENT

Plaintiff, the State of Ohio, by and through its Attorney General, Mike DeWine, demands a trial by jury on all claims to the maximum number of jurors permitted by law.

Mark H. Troutman (0076390)

DATED this 31st day of May, 2017.

Respectfully submitted,

STATE OF OHIO
MIKE DEWINE, ATTORNEY GENERAL

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